

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  03-302									
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>July 20, 2010</u>  Signature <u>/nancy joyce simmons/</u>  Typed or printed name <u>Nancy Joyce Simmons</u>	Application Number  10/816,677		Filed  April 2, 2004								
	First Named Inventor  Kinh-Luan (Lenny) Dao										
	Art Unit  1611		Examiner  Isis A.D. Ghali								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%; border: none;"><tr><td style="width: 50%; vertical-align: top; padding: 5px;"><input type="checkbox"/> applicant/inventor.</td><td style="width: 50%; vertical-align: top; padding: 5px;"><u>/David B. Bonham/</u> _____ Signature</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td style="vertical-align: top; padding: 5px;"><u>David B. Bonham</u> _____ Typed or printed name</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>34,297</u></td><td style="vertical-align: top; padding: 5px;"><u>703.433.0510</u> _____ Telephone number</td></tr><tr><td style="vertical-align: top; padding: 5px;"><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td style="vertical-align: top; padding: 5px;"><u>July 20, 2010</u> _____ Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<input type="checkbox"/> applicant/inventor.	<u>/David B. Bonham/</u> _____ Signature	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<u>David B. Bonham</u> _____ Typed or printed name	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>34,297</u>	<u>703.433.0510</u> _____ Telephone number	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	<u>July 20, 2010</u> _____ Date
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**Pending Claims**

Claims 1-5, 10-13, 15, 17-21 and 23-47 are pending in the application. Claims 2-4, 12-13, 15, 20-21, 24-25, 27-30, 33-38, and 44-45 are listed by the Examiner as withdrawn. Thus, Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 and 47 are presently under examination.

**Rejection Under 35 U.S.C. 112, Second Paragraph**

Applicant notes, with thanks, the Examiner's withdrawal of the rejection of claims 17 and 18 under 35 U.S.C. 112, second paragraph in the Advisory Action dated June 29, 2010.

**Rejection Under 35 U.S.C. 103(a) – Harish in view of Pilliar**

Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43 and 46-47 continue to be rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al., WO 02/26162 (Harish) in view of Pilliar, U.S. 3,855,638 (Pilliar). This rejection is in error.

As noted by the Examiner in the final Office Action, Harish teaches an implantable device coated on preselected regions/portions of its outer surface with therapeutic agent. The therapeutic agent is deposited on the surface of the device in the form of a dry stream of particles. The device is covered by a polymeric primer prior to applying the therapeutic particles to adhere the particles to the surface of the stent. The particles may be made of any substance suitable for loading onto implantable devices in solid form, including, but not limited to therapeutic substances or agents, radioisotopes, radiopaque substances, polymers, proteins, and nucleic acids (page 8, 1<sup>st</sup> full paragraph). Lists of therapeutic substances, radioactive/radiopaque substances, polymeric materials (including bioabsorbable polymers, polymeric biomolecules, and biostable polymers), proteins and nucleic acids are found on pages 9-11. The particles can be spherical having diameter from about 5 to 20 microns.

The Examiner further argues that “[a]lthough Harish teaches therapeutic particles coated as dry powder on a stent by virtue of adhesive [primer layer], and further teaches the particles may be made of different substances including biostable substances, however, the reference does not explicitly teach the therapeutic agent and the microparticles are separate entities as instantly claimed by amended claim 1.”

To make up for this deficiency, the Examiner turns to Pilliar. As noted in the Office Action, Pilliar teaches implantable devices partially coated with plurality of small discrete

metallic particles bonded together at points of contact with each other to define a plurality of pores in the coating and adhere to the device. The coating provides the device with uniform strength through the thickness of the coating. The pores of the implant may be treated with therapeutic agent such as materials that promote the tissue growth or antibiotics before implantation.

To form such a porous coating, Pilliar further teaches that a slurry of metallic powder suspended in aqueous solution with organic binders is applied to a substrate and heated to remove the water and finally sintered in an inert or reducing atmosphere, such as hydrogen, *to burn off the organic binder* and fuse the particles together and to the substrate (col. 7, lines 37-40).

In the particular embodiment of Example 1, an aqueous VITALLIUM powder slurry (VITALLIUM is a cobalt alloy) containing atomized VITALLIUM powder, methylcellulose, dioctyl sodium sulfosuccinate and ammonium hydroxide was made up and applied to a VITALLIUM rod to a depth of 1/32 inch. After drying, the coated rod was sintered at 2,200°F (i.e., white hot temperature) in a dry hydrogen atmosphere for approximately two hours, fusing the spherical powder particles at each contact point between themselves and the rod, and an interior communicating substantially uniform pore structure was evident.

On the basis of the above teachings the Examiner urges that the presently claimed invention is obvious, specifically arguing as follows (emphasis added):

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention *to provide an implantable device coated with dry powdered particles of therapeutic agents and other biostable substances adhered to the surface of the device by primer* as taught by Harish, and *replace the particle of the other biostable substances with the metallic particles taught by Pilliar that adhere together to form pores*. One would have been motivated to do so because Pilliar teaches that partial coating of implantable device with metallic particles provides the implantable device with uniform strength. *Further, one would have been motivated to apply therapeutic agent along with metallic particles* because Pilliar teaches that pores formed by the metallic particles can be treated with therapeutic agents before implantation. *One would reasonably expect formulating an implantable device coated with dry powdered particles of therapeutic agents and metallic particles that are adhered together forming pores and adhered to the surface of the device* wherein the device has sufficient strength and controllably releases the particles of the therapeutic agents.

Applicant respectfully disagrees.

One would not have been motivated to apply a therapeutic agent along with the metallic particles to an adhesive region in order to form an implantable device coated with dry powdered particles of therapeutic agents and metallic particles that are adhered together forming pores and adhered to the surface of the device. Moreover, one would not have arrived at the presently claimed invention by doing so. In this regard, claim 1 requires a “medical article comprising: (a) an adhesive region comprising an adhesive; (b) a therapeutic agent, wherein at least a portion of said therapeutic agent is adhered to a surface of said adhesive region; and (c) microparticles, at least a portion of which are adhered to said surface of said adhesive region...”

The statements in the preceding paragraph are true, because the adhesive region (i.e., prepolymer) taught by Harish and the therapeutic agents taught by Harish and Pilliar would be removed by the process of forming the porous coating that is taught by Pilliar. Specifically, the process taught by Pilliar involves heating a slurry of metallic powder suspended in aqueous solution with organic binders to remove the water, followed by sintering in an inert or reducing atmosphere, such as hydrogen, to *burn off the organic binder* and fuse the particles together and to the substrate. Such a process would clearly remove the prepolymer adhesive region taught by Harish. Such a process would remove as well the therapeutic agents taught by Harish and Pilliar. Consequently, one would not be motivated to carry out such a process and one would not arrive at the presently claimed invention by employing such a process.

In the Advisory Action, the Examiner argues (a) that Harish teaches therapeutic agents adhered to the surface of implantable devices as well as radio-isotopes and radiopaque substances, and further teaches biostable particles and (b) that Harish consequently suggests metallic particulates, but does not teach a mixture of metallic particulates and therapeutic particulates as separate entities.

In this regard, it should be noted that Harish teaches polymeric particles (including bioabsorbable polymers, polymeric biomolecules, and biostable polymers). Such a listing in Harish clearly does not rise to a suggestion of metallic particles are argued by the Examiner.

The Examiner further argues in the Advisory Action that Pilliar teaches metallic particulates and therapeutic agents and that Pilliar is relied upon for teaching partial coating of implantable device with metallic particles to provide the implantable device with uniform strength.

While it is true that Pilliar teaches that metallic particles can be used to form a coating of uniform strength, it is also true that these characteristic arise from bonding the particles to one another (col. 3, lines 9-60). Such bonded metallic particles are incompatible with the presently claimed microparticles, at least a portion of which are adhered to a surface of an adhesive region, because the process of Pilliar for forming such bonded metallic particles involves (a) heating a slurry of metallic powder suspended in aqueous solution with organic binders to remove the water, followed by (b) sintering in an inert or reducing atmosphere, such as hydrogen, *to burn off the organic binder* and fuse the particles together.<sup>1</sup>

Such bonded metallic particles are also incompatible with Harish, which describes adhesion of polymeric particles to a polymeric primer. See MPEP 2143.01 (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)): “If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” For example, in the present case, the formation of bonded metallic particles as described in Pilliar would render the adhesive polymeric primer unsatisfactory for its intended purpose (i.e., by destroying it).

The Examiner also argues in the Advisory Action that one would have been motivated to apply therapeutic agent along with metallic particles because Pilliar teaches that pores formed by the metallic particles can be treated with therapeutic agents before implantation. While applicant agrees that Pilliar teaches that pores formed by the metallic particles can be treated with therapeutic agents before implantation (col. 8, lines 27-31), this is a far cry from providing motivation to apply therapeutic agent *along with* metallic particles. As noted above, the processing described in Pilliar would result in the destruction of therapeutic agents.

In this regard, application of therapeutic agent along with metallic particles is *Applicant’s concept* and is only obvious in view of the teachings of Harish and Pilliar when coupled with the hindsight gained from applicant’s disclosure.

The Examiner additionally argues in the Advisory Action as follows (emphasis added): “One would reasonably expect formulating an implantable device coated with dry powdered particles of therapeutic agents and *metallic particles that are adhered together forming pores and adhered to the surface of the device* wherein the device has sufficient strength and

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<sup>1</sup> It is again noted that, in the Examples, a slurry coating is sintered at 2,200°F (i.e., *white hot temperature*) in a dry hydrogen atmosphere for approximately two hours.

controllably releases the particles of the therapeutic agents.” Applicant, again, disagrees, because (a) the present invention is not directed to metallic particles that are adhered together, but rather concerns microparticles that are adhered to a surface of an adhesive region, and (b) the processing described for forming such bonded metallic particles is incompatible with the claimed adhesive region and therapeutic agent.

Finally, in the last paragraph of the Advisory Action, the Examiner sets for various legal holdings from various federal cases, none of which are applied to the facts at hand and none of which negates the above-noted deficiencies in Harish and Pilliar and the above-noted reasons why their combined teachings do not render the present invention obvious.

For at least the above reasons, reconsideration and withdrawal of the rejection of the claims under 35 USC 103(a) are respectfully requested.

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